TESTIMONY BEFORE THE

HEALTH SUBCOMMITTEE

OF THE

HOUSE ENERGY AND COMMERCE COMMITTEE

ON

INCREASING GENERIC DRUG UTILIZATION: SAVING MONEY FOR PATIENTS

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Mr. Chairman and members of the Committee, my name is Bonnie Cramer. I am a member of AARP's Board of Directors. On behalf of our over 35 million members, thank you for convening this hearing and for including AARP in your discussions about the use of generic prescription drugs.

In November, millions of older Americans and those with disabilities will have the opportunity to choose to enroll in a long-overdue Medicare prescription drug benefit. Medicare coverage of prescription drugs will ensure that beneficiaries can afford necessary medications. However, even with the addition of this new benefit, more needs to be done to keep overall drug costs down. Generic drugs have an important role to play in helping to control drug prices for beneficiaries, the Medicare program, and for the entire health care system.

Rising Drug Prices

High prescription drug prices are taking a toll on our health care system – both the public and private sectors. Employer-sponsored health care premiums are rising at double digit increases,[1] in large part due to increasing prescription drug costs. As a result of rising health care costs, more employers are dropping coverage, thus increasing the number of uninsured Americans. There are currently more than 45 million Americans who lack health care coverage and

[1] Kaiser Family Foundation and Health Insurance and Educational Trust, Employer Health Benefits 2004 Summary of Findings.

these individuals pay the highest prices for their prescription drug needs. Many choose not to fill prescriptions because they cannot afford to pay for them. A recent AARP survey showed that among Americans age 50 and older, one in four said they decided against filling a prescription; cost was reported to be the main deterrent.[2]

Rising prescription drug prices continue to squeeze public programs at both the state and federal level. In 2003, the federal government spent $25.2 billion on prescription drugs for public programs.[3] Prescription drug spending in the Medicaid program increased at an average annual rate of 17 percent between 2000 and 2003.[4]

Generic Drugs Can Achieve Savings

Brand name prescription drug prices continue to rise at rates that are increasingly unaffordable for the average American. A recent AARP study revealed that, on average, pharmaceutical manufacturer prices for the 195 brand name drugs most widely used by older Americans increased at more than double

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[2] Prescription Drug Use Among Midlife and Older Americans, AARP, January 2005.

[3] Centers for Medicare and Medicaid Services, Expenditures for Health Services and Supplies Under Public Programs, by Type of Expenditure and Program: Calendar Year 2003, available at http://www.cms.hhs.gov/statistics/nhe/historical/t10.asp (noting that of this amount $5.3 billion was non-Medicaid dollars and $19.9 billion represented Medicaid spending on prescription drugs).

[4] John Holohan and Arunabh Ghosh, "Understanding the Recent Growth in Medicaid Spending, 2000-2003," Health Affairs, Jan. 26, 2005 at W5-52.

the rate of general inflation from 2000 through 2004.[5] The average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for these drugs was 7.1 percent in 2004, up from 4.1 percent in 2000. For the 153 brand-name drugs that were in the market for the entire five year period, this translates into a cumulative average price increase of over 35 percent, over two-and-one-half times the general inflation rate of 13.5 percent over the same period.

In contrast, generic drug prices are lower than brand name prescription drugs, and more interestingly, manufacturers' prices on generic drugs are not rising as fast as their brand name counterparts. A recent AARP study revealed that, on average, manufacturer list prices for the top 75 generic drugs most widely used by older Americans rose 0.5 percent in 2004 compared to a 13.3 percent average increase in 2003.[6] This average annual increase was less than one-fifth the rate of general inflation for 2004.

Generic Drugs Can be a Safe Alternative

In addition to generally being less expensive, generic drugs are also a safe alternative to brand name drugs. In order to gain Food and Drug Administration ("FDA") approval to market a generic drug, a manufacturer must demonstrate

[5] Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2004 Year-End Update, AARP Public Policy Institute Data Digest #DD112, April 2005.
[6] Trends in Manufacturer Prices of Generic Prescription Drugs Used by Older Americans, 2004 Year-End Update, AARP Public Policy Institute Data Digest #DD113, April 2005.

that the generic drug is bioequivalent to the comparable brand name prescription drug. To prove bioequivalence, the generic drug manufacturer must demonstrate two things. First, that the generic drug is pharmaceutically equivalent, in other words that it has the same active ingredients, strength, dosage, and method of administration as the brand name pharmaceutical. Second, the manufacturer must prove that the generic drug has comparable bioavailability, meaning that the generic drug must have the same rate and extent of absorption as the brand name pharmaceutical.

Nearly all generic drugs are expected to be bioequivalent to their brand name counterparts (e.g., "A"-rated generic drugs). For an overwhelming majority of individuals, these generic drugs can be safely substituted for the brand name equivalent drug. However, in a few limited cases, generic drugs may not meet the standards of therapeutic equivalency. These "B"-list drugs should not be substituted for the brand name drug.

There is documented evidence that suggests that for a small number of individuals, generic substitution may not be appropriate. For example, some individuals may be allergic to inert ingredients (e.g., coating) included in the generic drug. Therefore, AARP believes that prescribers must retain the ability to override generic substitution in cases when the prescribing physician has deemed such substitution to be medically appropriate (e.g., individual does not respond well to the generic drug treatment regimen).

Thus, a critical component of any drug formulary or preferred drug list that promotes use of generics is an efficient and effective exceptions process. Such a process should provide prompt access to a brand name or other appropriate drug whenever – based on sound clinical evidence provided by the prescribing physician – the generic is not medically appropriate for an individual patient. Equally important is ensuring that, whenever such exceptions are granted, the patient is not charged more for obtaining a medically appropriate drug. Furthermore, individuals who are granted such exceptions should not be required to go through the exceptions process again once it has been established that the generic is not medically appropriate for them.

Access to Generic Drugs

Use of generic drugs is steadily increasing. In 2001, generic drugs accounted for nearly half of all retail prescription drugs dispensed in the United States, up from 18.6 percent in 1984.[7] In 2003, generic drug prescriptions represented 43 percent of all prescriptions written, and 47 percent of new (non-refill) prescriptions.[8]

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, which helped

[7] Generic Drugs Research Report, AARP Public Policy Institute, publication IB61, May 2003.
[8] IMS Health, 2004.

speed generic drugs to market. Unfortunately, brand name pharmaceutical manufacturers have often tried to circumvent the Hatch-Waxman Act. Brand name pharmaceutical manufacturers facing loss of patent protection on blockbuster drugs began using litigation and other means to extend the life of patents. Courts and the Federal Trade Commission ("FTC") have determined that some brand name prescription drug manufacturers colluded with generic drug manufacturers to delay the marketing of competing generic products. The first generic version of a brand name drug to establish that it does not infringe on a valid patent receives a 180-day period of market exclusivity. Therefore, stopping or delaying market entry of the first generic drug prohibited all other generic drugs from competing, thus extending the brand name manufacturer's market exclusivity.

In another effort to extend the life of their patent protections, brand name manufacturers have also used the practice of "evergreening," the process of extending the patent protection of a brand name prescription drug as the term of the original patent nears expiration. One common method of evergreening is the "late-file patent", whereby brand name manufacturers change a small aspect of their drug (e.g., color, new dosage requirements, tablet shape) prior to the expiration of the patent and then obtain a new patent based on the "improvements" to the drug.

Evergreening blocks generic competition in at least two ways. First, after the slight change results in the granting of a new patent, the brand name manufacturer heavily promotes the "new" formulation as being much better than the old and creates enormous demand for the "new" product for which it can charge monopolistic prices. Thus, the market demand moves to the new expensive product even though there is little science-based evidence that the old product, for which generics may now be available, is inferior.

Second, brand name manufacturers used the late filed patents to manipulate the automatic 30-month stay of generic competition granted by Hatch-Waxman when the generic manufacturer notified the FDA that it would like approval to market a generic version of a brand name drug. The thirty months stay was designed to allow time for a court to resolve whether the generic infringes the brand name manufacturer's patent. But, after the first stay based on an older patent of a particular drug was resolved in favor of the generic, the brand name manufacturer then would file another suit against the generic based upon a later-filed patent on the same drug. This gave the brand name manufacturer another automatic 30-month stay preventing the generic manufacturer from bringing its drug to market until that patent issue was resolved. Brand name manufacturers were filing multiple challenges in order to extend their patent life. The Medicare Modernization Act of 2003 ("MMA"), bans this form of evergreening by limiting brand name pharmaceuticals to a single automatic 30-month stay.

Pharmaceutical innovation plays an important role in prolonging the life and improving the quality of life for individuals. Pharmaceutical manufacturers are rewarded for their innovations in the form of patents and FDA-granted market exclusivity on their products. However, the patent life of these innovator drugs should not be unnecessarily extended. Once the patent on the innovator drug has expired, generic drug manufacturers should not be hindered by unnecessary litigation and other efforts by the patent holder to extend patent protection beyond what true innovation deserves. There have been eleven successful challenges to patent laws brought by generic drug manufacturers; these challenges have provided over $27 billion in savings.[9]

Pharmaceutical companies that engage in actions to unnecessarily extend the life of their patent do so because holding the patent yields significant income for the company every year. However, this money is generated by individuals and health care payers. If generic drugs were brought to market in a timely manner, this could reap significant savings for the health care system in this country. AARP opposes patent extensions or extensions of market exclusivity.

In addition to bringing generics to market in a timely manner, the U.S. health care system can reap significant savings by investing heavily in the research of comparative clinical effectiveness of prescription drugs. Unlike in other countries, the U.S. does not require that drugs coming onto the market test better

[9] Generic Pharmaceutical Association's testimony to the HHS Task Force on Drug Importation, April 5, 2004.

than drugs already available in the marketplace. Funding of comparative clinical effectiveness studies would provide scientifically based information on the relative clinical effectiveness of different prescription drugs. In some cases the newer drug may be the best treatment option, in other cases the best treatment option may be the generic drug already on the market. Armed with this information, individuals and their prescribers can make better treatment decisions.

Consumer Education

Although Americans are becoming increasingly familiar with generics drugs – a recent AARP study showed that 97 percent of respondents say they have heard about generic prescription drugs[10] – some confusion about the benefits of generics still exits. Twenty-four percent of respondents indicated that generic drugs were different from brand name drugs, and among those who thought there was a difference, only four in ten believed generic drugs to be less effective. Surprisingly, overall only 21 percent of respondents believed generic drugs to be less expensive than brand name prescription drugs.

[10] Prescription Drug Use Among Midlife and Older Americans, AARP, Jan. 2005.

More education is needed to help consumers and physicians understand the benefits of generic drugs. Physicians generally support generic substitution,[11] but they also report frequent visits by brand name pharmaceutical manufacturer representatives, which can influence their prescribing behavior. Consumers also need to be aware that direct-to-consumer ("DTC") advertising often steers them towards brand name prescription drugs when a less costly generic and/or a less costly brand name drug may be available. Some DTC advertising is beneficial – such as advertising that raises awareness about certain diseases and/or conditions. However, the pharmaceutical industry spends billions of DTC advertising dollars to promote "new" formulation of products, which may show little improvement over less costly alternatives already available in the marketplace.

In April 2002, AARP launched a nationwide "Wise Use" campaign to promote the appropriate use of generic medicines. The campaign urged consumers to inform their doctor or pharmacist about all other medicines they were taking; to follow their physician's advice about exactly how to use their medicine properly; and to resist being pressured by direct-to-consumer pharmaceutical advertising to request an inappropriate or possibly unnecessary medicine. The campaign included print and broadcast ads, and a brochure, "Before You Take Your

[11] Physicians' Attitudes and Practices Regarding Generic Drugs, AARP, March 2005 (reporting that 78 percent of respondents support generic substitution in most cases, 17 percent support generic substitution in all cases where the generic drug is available, and only 5 percent do not support generic substitution).

Medicine, Take This Advice," developed with the American Pharmaceutical (now 'Pharmacists') Association, distributed in pharmacies nationwide.

This year, AARP took its education campaign further by unveiling a drug safety and effectiveness reference tool at http://www.aarp.org/health/comparedrugs. Based on the Drug Effectiveness Review Project conducted at the Oregon Health and Science University, AARP helps consumers compare the clinical and economic benefits of various drugs within common therapeutic categories. We urge consumers to review this information and, if applicable to their medical condition, to discuss it with their physician or other health care professional.

Conclusion

Generic drugs offer most Americans the same therapeutic value as brand name prescription drugs, but at a more affordable price. We urge Congress to do more to ensure that Americans have access to lower cost generic drugs as part of a broader agenda to bring down the rising cost of prescription drugs. AARP appreciates the opportunity to testify and we look forward to working with this Committee and Congress to help our members – and all Americans – understand the wise and safe use of generic drugs.